510(k) SUMMARY

MAR 2 9 2013

Flower Orthopedics Corporation's Flower Small and Medium Implants

Submitter's Name, Address, Telephone Number, Contact Person, and Date Prepared

Flower Orthopedics Corporation
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Date Prepared: March 29, 2013

Name of Device and Name/Address of Sponsor

Flower Small and Medium Implants

Common or Usual Name

Bone plating system

Classification Name/ Product Code

Classification Name: 21 CFR 888.3030 – Single/multiple component metallic bone fixation appliance and accessories

Product Codes: HRS (Plate, Fixation, Bone), HWC (Screw, Fixation, Bone)

Predicate Devices

Synthes USA's 3.5 mm and 4.5 mm Locking Compression Plate (LCP) System with Expanded Indications (K082807)
Synthes 3.5 mm and 4.5 mm Curved Narrow and Broad Locking Compression Plates (LCP) (K092609)
Stryker's VariAx Distal Radius Locked Plating System Line Extension for Addition of Aiming Blocks (K112455)
KLS-Martin Hand Plating System (K040598)
Synthes 2.4mm VA-LCP Intercarpal Fusion System (K103243)

Intended Use / Indications for Use

The Flower Small and Medium Implants set is intended for use for internal fixation of fractures and reconstruction of bones, including the scapula, olecranon, humerus, radius, ulna, pelvis, distal tibia, fibula, hand and foot in adults and for use in long bones in adolescents (12-21) in whom the growth plates have fused. Examples of these internal fixations and reconstructions include compression fractures, intra-articular and extraarticular fractures, displaced fractures, osteotomies, non-unions and mal-unions.

This system can be used for palmar, ventral, dorsal or orthogonal application.

Technological Characteristics

The Flower Small and Medium Implants set consists of the following components and accessories: pure titanium small straight plates, small and medium reconstruction plates, medium osteosynthesis plates, proximal humerus plates, distal radius plates, L-shaped plates, T-plates, angular T-shaped plates, H-shaped plates, mediocarpal plate; and titanium alloy screws. The device is also provided with general purpose instruments. All plates are made of pure titanium (ISO 5832-2).

The Flower Small and Medium Implants set provides fixed-angle lockable screws and plates to assist with internal fixation of fractures and reconstruction of bones. The principles of operation of the device are similar to other bone plating systems. The plates are comprised of various shapes, alignments, thicknesses, widths, and lengths designed to contour to different bones and locations on the body for internal fixation or reconstruction following fracture. Each of the plates contains several locking holes that allow for the insertion of Flower Small and Medium Implants locking screws. To use the Flower Small and Medium Implants set, the surgeon first selects an implant of the appropriate size and shape based on the intended site of use. The plate should be placed in an appropriate location on the given bone or anatomical location in need of repair.

Performance Data

In support of this 510(k) Premarket Notification, Flower Orthopedics has conducted the following testing. In all instances, the Flower Small and Medium Implants set functioned as intended.

- Biocompatibility in accordance with ISO 10993-1, ISO 10993-5 was established, demonstrating that the materials are non-cytotoxic and biocompatible.
- Sterilization validation of implants and instruments demonstrated assurance level of 10^{-6} for this method of sterilization using the specified gamma sterilization cycle.
- Packaging validation and shelf life testing ensured that the packaging can maintain its physical integrity and maintain a sterile barrier over the stated period.

Substantial Equivalence

The Flower Small and Medium Implants system is very similar to Synthes's 3.5 mm and 4.5 mm Locking Compression Plate (LCP) System with Expanded Indications (K082807), the Synthes 3.5 mm and 4.5 mm Curved Narrow and Broad Locking Compression Plates (LCP) (K092609), Stryker's VariAx Distal Radius Locked Plating System Line Extension for Addition of Aiming Blocks (K112455), KLS-Martin's Hand Plating System (K040598), and Synthes 2.4mm VA-LCP Intercarpal Fusion System (K103243). The Flower Small and Medium Implants system has the same intended

uses and similar indications, technological characteristics, and principles of operation as its predicate devices. The overall surgical procedure for the Flower Small and Medium Implants set and the predicate devices are very similar and there are no new types of safety or effectiveness concerns. The minor difference in the locking feature between the Flower system and the predicate systems do not significantly alter the surgical technique. The minor technological differences between the Flower Small and Medium Implants and its predicate devices, e.g., minor differences in the range of available geometries and dimensions, raise no new types of safety or effectiveness questions because these size differences are very minor and are largely encompassed within the range of similar parameters in the predicate devices. Engineering analysis has been performed to demonstrate that the Flower Small and Medium Implants system provides appropriate mechanical strength for its intended use. Thus, the Flower Small and Medium Implants system is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Flower Orthopedics Corporation
% Hogan Lovells US LLP
Ms. Janice M. Hogan, Partner
1835 Market Street, 29th Floor
Philadelphia, Pennsylvania 19103

Letter dated: March 29, 2013

Re: K123562
Trade/Device Name: Flower Small and Medium Implants
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: March 1, 2013
Received: March 1, 2013

Dear Ms. Hogan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K123562

Device Name: Flower Small and Medium Implants

Indications for Use:

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This system can be used for palmar, ventral, dorsal or orthogonal application.

Prescription Use ____X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Krishna R. Asundi
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